

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63897, Dec. 12, 1994]

§ 184.1914 Trypsin.

(a) Trypsin (CAS Reg. No. 9002–07–7) is an enzyme preparation obtained from purified extracts of porcine or bovine pancreas. It is a white to tan amorphous powder. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.21.4).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995]

§ 184.1923 Urea.

(a) Urea ($\text{CO}(\text{NH}_2)_2$, CAS Reg. No. 57–13–6) is the diamide of carbonic acid and is also known as carbamide. It is a white, odorless solid and is commonly produced from CO_2 by ammonolysis or from cyanamide by hydrolysis.

(b) FDA is developing food-grade specifications for urea in cooperation with the National Academy of Sciences. In the interim, this ingredi-

ent must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in § 170.3(o)(14) of this chapter and as a fermentation aid.

(2) The ingredient is used in yeast-raised bakery products; in alcoholic beverages as defined in § 170.3(n)(2) of this chapter; and in gelatin products.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51616, Nov. 10, 1983, as amended at 49 FR 19816, May 10, 1984]

§ 184.1924 Urease enzyme preparation from *Lactobacillus fermentum*.

(a) This enzyme preparation is derived from the nonpathogenic, nontoxicogenic bacterium *Lactobacillus fermentum*. It contains the enzyme urease (CAS Reg. No. 9002–13–5), which facilitates the hydrolysis of urea to ammonia and carbon dioxide. It is produced by a pure culture fermentation process and by using materials that are generally recognized as safe (GRAS) or are food additives that have been approved for this use by the Food and Drug Administration (FDA).

(b) The ingredient meets the general and additional requirements for enzyme preparations in the "Food Chemicals Codex," 3d ed. (1981), pp. 107–110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct human food ingredient is based

upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in wine, as defined in 27 CFR 2.5 and 4.10, as an enzyme as defined in §170.3(o)(9) of this chapter to convert urea to ammonia and carbon dioxide.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Current good manufacturing practice is limited to use of this ingredient in wine to inhibit formation of ethyl carbamate.

[57 FR 60473, Dec. 21, 1992]

§ 184.1930 Vitamin A.

(a)(1) Vitamin A (retinol; CAS Reg. No. 68-26-8) is the alcohol 9,13-dimethyl-7-(1,1,5-trimethyl-6-cyclohexen-5-yl)-7,9,11,13-nonatetraen-15-ol. It may be nearly odorless or have a mild fishy odor. Vitamin A is extracted from fish liver oils or produced by total synthesis from β -ionone and a propargyl halide.

(2) Vitamin A acetate (retinyl acetate; CAS Reg. No. 127-47-9) is the acetate ester of retinol. It is prepared by esterifying retinol with acetic acid.

(3) Vitamin A palmitate (retinyl palmitate; CAS Reg. No. 79-81-2) is the palmitate ester of retinol. It is prepared by esterifying retinol with palmitic acid.

(b) The ingredient meets the specifications for vitamin A in the Food Chemicals Codex, 3d Ed. (1981), p. 342, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good man-

ufacturing practice. Vitamin A may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51610, Nov. 10, 1983]

§ 184.1945 Vitamin B₁₂.

(a) Vitamin B₁₂, also known as cyanocobalamin (C₆₃H₈₈CoN₁₄O₁₄P, CAS Reg. No. 68-0919-099), is produced commercially from cultures of *Streptomyces griseus*.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 343, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Vitamin B₁₂ also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 6341, Feb. 15, 1985]

§ 184.1950 Vitamin D.

(a) Vitamin D is added to food as the following food ingredients: